

Claims:

1. An airway device for human or animal use comprising an airway tube having a distal end and a proximal end, the distal end of which is surrounded by a laryngeal cuff, wherein the cuff is non-inflatable and is pre-formed in a shape such that a face region of the cuff is adapted to fit snugly over the laryngeal inlet of a patient, and wherein the external profile of the tube is substantially uniform between the distal end of the tube where it starts to meet the cuff and the proximal end of the tube, and wherein the face region of the cuff is formed from a material with a Shore hardness on the A scale of between 0 to 30.
2. An airway device as claimed in Claim 1 wherein the face region of the cuff is formed from a material of Shore hardness on the A scale of between 0 and 20.
3. An airway device as claimed in Claim 1 or Claim 2 wherein the cuff is formed from a material of Shore hardness on the A scale of between 0 and 5.
4. An airway device as claimed in any preceding claim wherein the profile of the airway tube is substantially circular.
5. An airway device as claimed in any of Claims 1 to 3 inclusive wherein the profile of the airway tube is substantially elliptical.
6. An airway device as claimed in any preceding claim wherein the device further comprises a gastric tube passageway extending from the distal end of the airway tube to the proximal end of the cuff.
7. An airway device as claimed in Claim 6 wherein the gastric tube passageway is housed substantially within the body of the device.
8. An airway device according to Claim 6 or Claim 7 wherein the distal end exit of the gastric tube passageway exits the cuff centrally, that is along the line of the central longitudinal axis of the device.

- 5 9. An airway device according to Claim 6 and Claim 7 wherein the distal end exit of the gastric tube passageway is displaced to one side of the central longitudinal axis of the device.
- 10 10. A device according to any preceding claim wherein the device further comprises one or more flexible flanges extending around the opening in the face region of the cuff.
- 11 11. A device according to Claim 10 wherein the flexible flanges extend substantially around the entire circumference of the opening in the cuff.
- 15 12. A device according to Claim 10 or Claim 11 wherein a plurality of flanges are provided said flanges being space apart radially around the opening one from another such that the flanges are substantially concentric.
- 20 13. A device according to any preceding claim wherein said device further comprises a connector adapted to connect the proximal end of the airway tube to a gas supply.
- 25 14. A device according to Claim 13 wherein said connector extends into said airway tube and at least part way along the length of said airway tube to act as a bite protector to prevent a patient from constricting the airway tube by biting on it.
- 30 15. A device as claimed in Claim 13 or Claim 14 wherein said connector fits into an internal annular recess at the proximal end of the airway tube such that the diameter, or internal cross-section of the airway tube where the tube is non-circular internally, remains substantially constant along the length of the tube when the connector is in place.
16. An airway device according to Claim 15 wherein the distal end of the connector abuts in use a shoulder in the airway tube to prevent the connector from passing into the airway tube beyond a certain point.

17. An airway device according to any preceding claim wherein the face of the laryngeal cuff is adapted to form an anatomical fit over the laryngeal inlet of a patient incorporates protuberances designed to form a good seal with the pyriform fossae and aryepiglottic folds of the laryngeal inlet of the patient.

18. An airway device according to Claim 17 wherein the face of the laryngeal cuff adapted to form an anatomical fit over the laryngeal inlet of a patient incorporates protuberances designed to form a good seal with the valleculae, epiglottis, aryepiglottic folds, pyriform fossae and around the thyroid & cricoid cartilages.

19. An airway device according to any preceding claims wherein the face of the laryngeal cuff adapted to fit anatomically over the laryngeal framework of a patient incorporates grooves designed to allow passage of vital arteries, veins and nerves supplying the laryngeal framework.

20. An airway device according to any preceding claim wherein the distal tip of the laryngeal cup is so sized and shaped as to remain above the upper oesophageal sphincter in use.

21. An airway device according to Claim 20 wherein the distal tip of the laryngeal cup is substantially concave in shape.

22. An airway device as claimed in any preceding claim wherein the face of the laryngeal cuff and the airway tube are formed from material of substantially the same Shore hardness.

23. An airway device as claimed in any of Claims 1 to 21 inclusive wherein the face of the laryngeal cuff and the airway tube are formed from materials of different Shore hardness.

24. An airway device as claimed in any of Claims 1 to 18 inclusive wherein the airway tube together with the back or dorsal part of the cuff are made from material of

one Shore hardness and the face of the cuff is made from a material of a different Shore hardness, such that the face of the cuff is made of a softer material than the airway tube and the back or dorsal part of the cuff.

5 25. An airway device substantially as herein described with reference to and as illustrated in any combination of the accompanying drawings.

26. A method of manufacturing an airway device suitable for human or animal use, said airway device comprising an airway tube having a distal end and a proximal end,
10 the distal end of which is surrounded by a non-inflatable laryngeal cuff, said method comprising the steps of:-

- (i) providing a mould, the mould including interior walls defining an interior volume which defines the shape of the airway device;
- (ii) introducing a liquid plastics material into the hollow interior volume of the mould;
- 15 (iii) optionally introducing a second liquid plastics material into said mould where it is required that the airway device is made from materials of different Shore hardness;
- (iv) allowing the plastics material to solidify;
- (v) removing the airway device from the mould.

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27. A method according to Claim 26 wherein said method also comprises the step of inserting into said mould a connector suitable for connecting to an anaesthetic gas supply, such that, after the moulding process is complete, the connector becomes attached to the airway device.

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28. A method of manufacturing an airway device suitable for human or animal use, said airway device comprising an airway tube having a distal end and a proximal end, the distal end of which is surrounded by a non-inflatable laryngeal cuff, said method comprising the steps of:-

- 30 (i) providing an airway tube;
- (ii) providing a mould, said mould including interior walls defining an interior volume which defines the shape of a laryngeal cuff;
- (iii) inserting said airway tube into said mould;

- (iv) introducing a liquid plastics material into the hollow interior volume of the mould;
- (v) optionally introducing a second liquid plastics material into said mould where it is required that the cuff of the airway device is made from materials of different Shore hardness;
- 5 (vi) allowing the plastics material to solidify;
- (vii) removing the airway device from the mould.

29. A method according to Claim 28 wherein said airway tube is formed by an extrusion process.

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30. A method of manufacturing an airway device suitable for human or animal use, said airway device comprising an airway tube having a distal end and a proximal end, the distal end of which is surrounded by a non-inflatable laryngeal cuff, said method comprising the steps of:-

- 15 (i) providing a mould, the mould including interior walls defining an interior volume which defines the shape of a laryngeal cuff;
- (ii) introducing a liquid plastics material into the hollow interior volume of the mould;
- (iii) optionally introducing a second liquid plastics material where it is required that the airway device is made from materials of different Shore hardness;
- 20 (iv) allowing the plastics material to solidify;
- (v) removing the airway device from the mould;
- (vi) providing an airway tube;
- (vii) attaching said airway tube to said laryngeal cuff.

25 31. A method of manufacturing an airway device suitable for human or animal use, said airway device comprising an airway tube having a distal end and a proximal end, the distal end of which is surrounded by a non-inflatable laryngeal cuff, said method comprising the steps of:-

- (i) providing an airway tube;
- 30 (ii) providing a mould, said mould including interior walls defining an interior volume which defines the shape of a laryngeal cuff and which substantially encapsulates the airway tube;
- (iii) inserting said airway tube into said mould;

- (iv) introducing a liquid plastics material into the hollow interior volume of the mould, to form the back of the cuff and substantially cover the rigid airway tube
 - (v) optionally introducing a second liquid plastics material into said mould where it is required that the cuff of the airway device is made from materials of different Shore hardness;
 - (vi) allowing the plastics material to solidify;
 - (vii) removing the airway device from the mould.
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32. A method according to Claim 31 wherein the airway tube is formed by an extrusion process.
33. A method of manufacturing an airway device substantially as herein described.